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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/069,228	04/27/1998	GREGORY D. PLOWMAN	234/118	3164

7590

07/23/2002

Beth A. Burrous or John P. Isacson  
FOLEY & LARDNER  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, DC 20007-5109

EXAMINER

CANELA, KAREN A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 07/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.  
09/069,228

Applicant(s)  
Plowman et al

Examiner  
Karen Canella

Art Unit  
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Mar 11, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s):  
see attached
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see attached
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: none
- Claim(s) objected to: none
- Claim(s) rejected: 2-5, 9, and 23-37
- Claim(s) withdrawn from consideration: \_\_\_\_\_
8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

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***Response to Arguments***

1. The rejection of claims 9, 23-26, 28, 35 and 36 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of applicant's arguments.
2. The rejection of claims 2-5, 9 and 23-37 under 35 U.S.C. 101 because the claimed invention is not supported by either a asserted utility or a well established utility is maintained for reasons of record.
3. The rejection of claims 2-5, 9 and 23-37 under 35 U.S.C. 112, first paragraph for lacking a utility is also maintained for reasons of record.
4. Applicant has supplied a post-filing date reference (Jornvall et al, JBC, 2001, Vol. 276, pp. 5140-5146) as proof that the claimed ALK-7 has utility as it plays a role in cell cycle arrest and morphological differentiation. Applicant's have also supplied the reference of Leopold (Oncogene 200, Vol. 19, pp. 6594-6599) who teaches that targeting of cancer therapy to pharmacological intervention with the MAP kinase pathway. Applicant concludes that since ALK-7 activates the MAP kinase pathway it therefore has utility based on the teachings of Leopold. Both of these arguments have been considered but not found persuasive. Discoveries of utility occurring after the filing date, i.e. identification ALK-7 as signaling cell cycle arrest and differentiation in neuronal cells, are of no consequence regarding what one of skill in the art believed as of the filing date. See *In re Wright*, 27USPQ 1510, 1514 (Fed. Cir. 1993). Furthermore, the instant specification must assert the a specific, substantial and credible utility at

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the time of filing. The instant specification did not identify the utility taught by Jornvall in the specification. The specification identified ALK-7 as a type I serine/threonine kinase receptor expressed in the hippocampus, hypothalamic nuclei, substantia nigra and pituitary. The specification did not identify the type II receptor associated with ALK-7 although the specification teaches that the type II receptor is necessary for activation of a type I receptor such as ALK-7. Further the specification did not identify the resulting signal which would be transmitted by cross phosphorylation of the unidentified type II receptor and ALK-7. Therefore, such a utility as proposed by Leopold cannot be based on the specification as filed as there was no disclosure of ALK-7 activating the MAP kinase pathway. The M.P.E.P.(715.07) states that a utility must be known before reduction to practice can occur (In re Wilkinson, 304 F.2d 673, 134 USPQ 171 (CCPA 1962)). As the instant specification was lacking a specific, substantial and credible asserted utility at the time of filing, proof of a specific, substantial and credible utility after the filing date has no bearing on the instant rejection.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

July 15, 2002



ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600